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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,930	12/04/2006	David Platt	89918.021302	7979
32361	7590	12/23/2008		
GREENBERG TRAURIG, LLP				
MET LIFE BUILDING				
200 PARK AVENUE				
NEW YORK, NY 10166				
EXAMINER				
BLAND, LAYLA D				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
12/23/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/597,930

**Applicant(s)**

PLATT ET AL.

**Examiner**

LAYLA BLAND

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-6 and 8-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is a response to Applicant's amendment submitted October 1, 2008, wherein claims 1 and 7 are canceled, claims 2-6, 8-10, and 15 are amended, and claim 16 is newly submitted.

Newly submitted claim 16 and amended claim 10 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented method of treating a dermatological condition which is acne or candida and the newly submitted method of treating trichomonas are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a different mode of operation, function and effect. Treatment of a dermatological condition caused by candida, which causes skin infection such as acne, comprises treatment of a fungal infection of the skin. Treatment of trichomonas comprises treatment of a bacterial infection of the vagina or male urinary tract. The methods are mutually exclusive because one requires treatment of a subject having acne or candida, not required by the newly submitted method claims, and the newly submitted method claim requires treatment of a subject infected with trichomonas, not required by the originally presented claims. Furthermore, the inventions as claimed do not encompass

overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10-12 (in part) and claim 16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 2-6 and 8-15 are examined on the merits herein.

### ***Priority***

The provisional application 60/544,402, upon which priority is claimed, fails to provide adequate support under 35 U.S.C. 112 for claims 2-6 and 8-15 of this application since the priority application does not disclose "x at least about 0.15," N is "between about 10 and about 100," or molecular weight "about 20 kDa to about 80 kDa."

Thus, the filing date of claims 2-6 and 8-15 is deemed to be the instant filing date, February 14, 2005. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In view of the cancellation of claims 1 and 7, all rejections made with respect to those claims in the previous office action are withdrawn.

The objection to claims 2 and 3 for misspellings is withdrawn.

In view of Applicant's amendment submitted October 1, 2008, all prior art rejections made in the previous office action are withdrawn in favor of new rejections which will be presented below.

The following new rejections were necessitated by Applicant's amendment submitted October 1, 2008, wherein the molecular weight range was narrowed, the value of x was changed, and the range of N was narrowed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 9 and 15 were amended such that "x is at least about 0.15." The specification as originally filed provides support for x between 0.01 and 0.3, but does not provide support for x being "at least about 0.15" with no upper limit.

Claims 6 and 9 and 15 were amended such that N is "between about 10 and about 100." The specification as originally filed provides support for N between about 1 and 100, but does not provide support for N between 10 and 100.

Claims 6 and 9 and 15 were amended such that the molecular weight is in the range of "about 20 kDa to about 80 kDa." The specification as originally filed provides support for a range of 15-80 kDa but not for 20-80 kDa.

"New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement," and "a subgenus is not necessarily described by a genus encompassing it and species upon which it reads." See *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972); MPEP 2163.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-5 depend from claim 6 and recite the limitations "said carbohydrate" and "said antimicrobial agent." Claim 6 does not recite "carbohydrate" or "microbial agent." There is insufficient antecedent basis for these limitations in the claims.

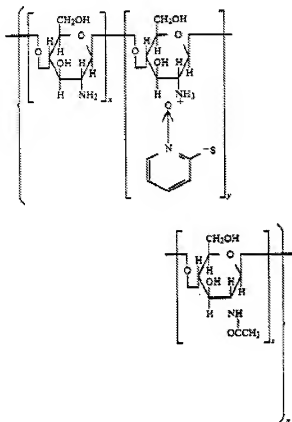
***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 5,015,632, May 14, 1991, of record) in view of Seo et al. (SOFW-Journal, 128, January 9, 2002, pages 46-51).

Nelson teaches a chitosan pyrithione salt which is useful as an antimicrobial agent in soaps, shampoos, and skin care medicaments [see abstract]. The effective amount is between about 0.1 and 30 weight percent based on the total weight of the personal care product [column 2, lines 44-50]. Chitosan has fungicidal and wound-healing activity and pyrithione salts have antibacterial and antifungal activity [column 1, lines 17-26]. The MIC of chitosan pyrithione for *Candida albicans* was 2 ppms [column 5, Table 1]. In the chitosan pyrithione salt, shown below, x, y and z are independently 0.01-0.98 and n is 700-10,000 [column 1, lines 35-68]. The molecular weight is between 150,000-600,000.



Nelson et al. do not teach chitosan pyrrhione having N 10-100 and molecular weight 20-80 kDa.

Seo teaches that chitosans having molecular weight in the range of 5,000-200,000 Da have potent anti-microbial activity [page 48, last paragraph]. Chitosan of MW of about 75,000 Da was exemplified and was effective for *Candida albicans* [page 48, Table 1 and Table 2].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use low molecular weight chitosan in the antimicrobial composition taught by Nelson et al. Seo teaches that the above described chitosans were water soluble and had anti-microbial activity. Thus, the skilled artisan could



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conceive of using Seo's chitosans in an antimicrobial composition and could have predicted that the resulting composition would have been an effective antimicrobial. It would have been further obvious to use the resulting composition for treating a dermatological condition because Nelson teaches that the compositions are useful as skin medicaments [column 1, lines 24-26]. It would also have been obvious to include decyl polyglucose in a skin care composition. Decyl glucose is a surfactant commonly used in personal care products; thus, it would have been obvious to include it in the compositions taught by Nelson, which are taught to be useful as soaps, shampoos, and skin medicaments. One of ordinary skill in the art could find the optimal concentrations for treating various skin conditions via routine experimentation.

### ***Response to Arguments***

Applicant's arguments regarding the molecular weights of the products cited in Nelson, Platt, and Yaku are moot in view of the new ground of rejection.

Applicant argues that Nelson does not disclose the use of chitosan material that is more than approximately 10% acetylated. Although Nelson teaches one example wherein the chitosan was 89.4% deacetylated, Applicant's argument is not persuasive because Nelson teaches that  $z$  (molar equivalents of N-acetylglucosamine) should be between 0.01 and 0.98 [claim 1], which meets the limitation "at least about 0.15."

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/  
Examiner, Art Unit 1623